

1636  
2hw/B

Effective on 12/08/2004.  
Pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	(\$)	180.00
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**Complete if Known**

Application Number	09/393,844
Filing Date	09/10/1999
First Named Inventor	Katherine A. High et al.
Examiner Name	Sullivan, Daniel M.
Art Unit	1636
Attorney Docket No.	018743-0276322

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account    Deposit Account Number: 50-2212    Deposit Account Name: Pillsbury Winthrop LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below    ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17    ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

**Total Claims**    **Extra Claims**    **Fee (\$)**    **Fee Paid (\$)**    **Multiple Dependent Claims**

         - 20 or HP = 0 x 25 = 0    **Fee (\$)**    **Fee Paid (\$)**

HP = highest number of total claims paid for, if greater than 20

**Indep. Claims**    **Extra Claims**    **Fee (\$)**    **Fee Paid (\$)**

         - 3 or HP = 0 x 100 = 0

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

**Total Sheets**    **Extra Sheets**    **Number of each additional 50 or fraction thereof**    **Fee (\$)**    **Fees Paid (\$)**

         - 100 =          / 50 =          (round up to a whole number) x          =         

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

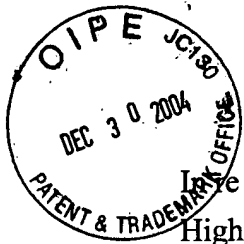
Other: Submission of Information Disclosure Statement    **Fees Paid (\$)**

180.00

<b>SUBMITTED BY</b>		Registration No.	Telephone
Signature		(Attorney/Agent) 43488	858-509-4065
Name (Print/Type)	Robert M. Bedgood	Date	December 28, 2004

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: PATENT APPLICATION OF  
High, et al.

Confirmation No.: 3411

Appln. No.: 09/393,844

Group Art Unit: 1636

Filed: September 10, 1999

Examiner: Sullivan, Daniel M.

Title: METHODS AND COMPOSITIONS FOR USE IN GENE THERAPY FOR  
TREATMENT OF HEMOPHILIA

**TRANSMITTAL LETTER**

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Certificate of Mailing Under 37 C.F.R. §1.8**

I hereby certify that this correspondence along with any paper referred to as being attached is being Mailed to Addressee by service of the United States Postal Service addressed to Commissioner for Patents, P.O. Box, 1450, Alexandria, VA 22313-1450

Date: December 28, 2004 By: 

Sachiko Y. Snedden

Sir:

Transmitted herewith for filing are the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copy of Supplementary European Search Report mailed October 11, 2004;
4. Copy of Supplementary Partial European Search Report mailed July 23, 2004;
5. Cited References (9);
6. Fee Transmittal; and
7. Return Postcard.

A fee in the amount of \$180.00 is incurred for filing this Statement. The Commissioner is hereby authorized to charge any fee that may be due in connection with this and the attached papers, or with this application during its entire pendency, or to credit any overpayment to Deposit Account 50-2212, Order No. 018743-0276322. A duplicate of this Transmittal is enclosed.

Respectfully submitted,

Pillsbury Winthrop LLP

Date: December 28, 2004

11682 El Camino Real, Suite 200  
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By: 

Robert M. Bedgood, Ph.D.  
Reg. No. 43,488  
Tel. No. (858) 509-4065  
Fax No. (858) 509-4010

Docket Number: 018743-0276322

PATENT APPLICATION

Client Reference: CHOP-00004U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of  
CATHERINE A HIGH, et al.

Group Art Unit: 1636

Application No.: 09/393,844

Examiner: Sullivan, Daniel M.

Filed: September 10, 1999

Confirmation No.: 3411

For: METHODS AND COMPOSITIONS FOR USE IN GENE THERAPY F OR TREATMENT  
OF HEMOPHILIA

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. Applicants respectfully request the Examiner return an initialed copy of the enclosed Form PTO-1449 to Applicants with the next Office communication to indicate that the reference(s) has been considered, per MPEP § 609.

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**CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10\***

(When using Express Mail, the Express Mail label number is *mandatory*; Express Mail certification is *optional*.)

I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: December 28, 2004

01/03/2005 CCHAU1 00000002 502212 09393844

01 FC:1806 180.00 DA

Signature

SACHIKO Y. SNEDDEN

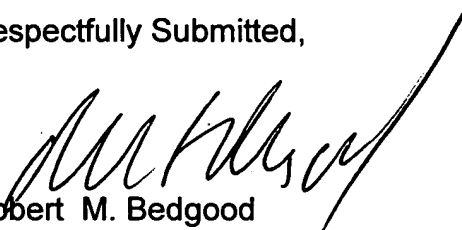
(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Please charge Deposit Account 502212, Order No. 018743-0276322, in the amount of \$180.00 in payment of the fee under 37 CFR 1.17(i)(p). Please credit or debit Deposit Account 502212 as needed to ensure consideration of the disclosed information.

The reference(s) was/were cited in a counterpart foreign application. Two English language version of the foreign search reports are attached for the Examiner's information.

Respectfully Submitted,



Robert M. Bedgood  
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Customer Number: 27500

Date: December 28, 2004  
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Atty. Dkt. No.	C-M#	Client Ref.
	018743-0276322	
Applicant: High, et al.		
Appln. No.: 09/393,844		
Filing Date: September 10, 1999		
Examiner: Sullivan		Art Unit: 1636

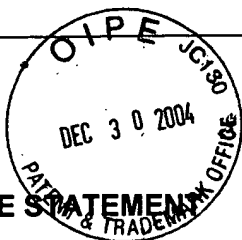
Date: December 28, 2004	Page	1	of	2
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**Date Considered:**

**PAT-1449 12/98**

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**



018743-0276322

**Examiner: Sullivan**

Art Unit: 1636

Page

2

of

2

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

English

### Translation

**Examiner's**

## Abstract

**Readily  
Available**

Initials\*

**Enclosed**

E

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**No**

[illegible]

CR

Gnatenko et al., "Generation and Characterization of Recombinant Adeno-Associated Viral (rAAV) Vectors for Factor VIII Gene Therapy", *Blood*, 1996; 88(10) SUPP. 01 Part 01/2): 139A, Abstract 543, XP001053457

DR

Kessler et al., "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein", *Proc. Natl. Acad. Sci. USA*, 1996; 93(24): 14082-14087, XP002287407

ER

Koeberl et al., "Persistent expression of human clotting factor IX from mouse liver after intravenous injection of adeno-associated virus vectors", *Proc. Natl. Acad. Sci. USA*, 1997; 94(4): 1426-1431, XP002287408

FR

Chen et al., "Comparison of Retroviral and Adeno-Associated Viral Vectors Designed to Express Human Clotting Factor IX", *Human Gene Therapy*, 1997; 8(2): 125-135, XP009029448

**GR**

Wiener et al., "Stable Production in Vitro of Human Coagulation Factor IX Expressed from Adeno-Associated Virus", Blood, 1996; 88(10) SUPPL. 1 Part 1-2): 138A, Abstract 541, XP008032518

HR

Kotin, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy", Human Gene Therapy, 1994; 5: 793-801, XP002911111

IR

Database Biosis [Online] Biosciences Information Service, Philadelphia, PA, US; 1997, Fisher et al: "Recombinant adeno-associated virus for muscle directed gene therapy". Abstract, XP002287409

**Date Considered:**

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.